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Behavioral Interventions Versus Pharmaceutical Interventions to Reduce Preoperative Anxiety in School Aged Children

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BEHAVIORAL INTERVENTIONS VERSUS PHARMACEUTICAL
INTERVENTIONS TO REDUCE PREOPERATIVE ANXIETY IN SCHOOL
AGED CHILDREN.

by

JENNIFER CLINE

A thesis submitted in partial fulfillment of the requirements
for Honors in the Major Program in Nursing
in the College of Nursing
and in the Burnett Honors College
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ABSTRACT

Surgical procedures that require general anesthesia can be stressful and create needless anxiety for school-age children. Interventions aimed at reducing preoperative anxiety can improve cooperation and enhance postoperative outcomes by lowering anxiety levels prior to induction of general anesthesia. The purpose of this study was to examine the effects of behavioral interventions versus drug therapy in reducing pre-operative anxiety in children. The secondary purpose was to compare methods used to integrate anxiety reduction interventions into pre-operative care and to evaluate the most widely used and effective strategy for clinical practice. A literature review exploring behavioral based stress reduction interventions and drug therapy targeted at reducing preoperative anxiety was conducted from various online databases. Peer reviewed articles, published in the English-language between 2006 and 2015 that focused on postoperative outcomes in which preoperative interventions to reduce anxiety in children age two years and older, as well as the parent's perspective of the outcome, were included for synthesis. Results from 9 randomized controlled trials that used behavioral based interventions implemented on the day of surgery, prior to anesthesia induction were compared for effectiveness at anxiety reduction versus the use of drug therapy prior to surgery. The studies suggest more successful post-surgical outcomes related to shorter length of stay and post-operative delirium for behavioral interventions to reduce anxiety prior to surgery and demonstrated even greater optimal outcomes for combined behavioral interventions. Drug therapy alone to decrease anxiety prior to anesthesia induction showed mixed results in reduction of physiologic and general outcomes following surgery. No significant difference between

behavioral based interventions versus drug therapy was shown in any of the reviewed studies to have a significant effect on post-surgical outcomes. However, potentially promising behavioral based interventions such as clowns, electronic devices, parental presence and music over drug therapy prior to surgery, require further evaluation for their use in decreasing pre-operative anxiety in school-age children and having a positive impact on post-operative outcomes.

DEDICATIONS

For my mentor, Dr. Leslee D'Amato-Kubiet; for giving the encouragement, support and guidance to push me at the starting line and cheer me on through the finish line; while reminding me to never quit running and always look for the next race!!

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INTRODUCTION

Preoperative anxiety and stress represent complex emotions often experienced by children and their parents prior to an invasive, surgical procedure. Preoperative anxiety and stress in children has been linked to an increased occurrence of postoperative delirium, increased negative behaviors, and exacerbation of postoperative pain. Interventions directed at reducing anxiety and stress during the preoperative period can be useful in assisting healthcare providers to improve post-operative health and wellness outcomes in children and their family.

Examining preoperative anxiety in children is critical because higher levels of anxiety can result in less desirable post-operative outcomes. Factors that cause anxiety in children prior to surgical procedures is poorly understood and methods to reduce anxiety have no practical foundation for effectiveness. Interventions aimed at minimizing preoperative anxiety, such as interactive tools and parental presence during induction of anesthesia, are vastly understudied. Reducing preoperative anxiety in children can improve postoperative outcomes such as reducing hospital length of stay, decreasing recovery times, enhancing parent-child dyad satisfaction of care, and decreasing psycho-social emergence delirium. Exploring the use of preoperative behavioral based interventions that include technological apparatuses, parent interactions and various distracting techniques including coloring, reading, crafting and a clown, are expected to improve postoperative outcomes in school-age children.

PROBLEM

There is evidence that both drug therapy and behavioral interventions can reduce a child's anxiety, but the research lacks the comparison of the two with the optimization of reduction in preoperative patients. Therefore, leading one to question as to which intervention can enhance outcomes benefiting hospitals, children and their parents by reducing anxiety.

Reduction of a child's preoperative anxiety can be approached using both drug therapy and behavioral based methods. Exploring the outcomes of the different interventions can help determine if there is a difference between pre-operative drug therapies or behavioral directed interventions in children that will produce improved post-operative outcomes. For example, allowing a child to pick out an age appropriate game to play on a tablet-style computer could reduce anxiety preoperatively through distraction and engage the child in mindful entertainment without the need for drug therapy interventions. It is expected that behavior-based techniques to decrease anxiety could optimize post-operative outcomes.

Although administration of drug therapy prior to a surgical procedure can produce a reduction in anxiety in children, it can lead to undesirable side-effects, adverse effects, and even serious, life threatening consequences. Exploring drug therapy and behavioral based interventions and their effectiveness in decreasing pre-operative anxiety in children can be of value to the health care team in general, and nurses in particular for improving post-operative outcomes: such as reduction in emergence from anesthesia delirium and time to recovery.

Understanding and exploring interventions directed at the reduction of pre-operative anxiety in children can benefit the child's health if the need for drug therapy prior to a surgical

procedure is diminished or reduced. The findings could potentially affect hospitals financially, with shorter length of stays and increased satisfaction for the parents of hospitalized children.

PURPOSE

The purpose of this study is to review and critique current research that examines the effects of behavioral versus pharmaceutical drugs interventions in reducing pre-operative anxiety in children. This review is expected to provide better understanding of how pre-operative anxiety reduction with or without the use of drug therapy interventions impacts children's post-surgical outcomes. The author proposes that behavioral interventions prior to surgery in children can improve post-operative outcomes by decreasing emergence delirium and shortening hospital length of stay after surgical procedures. The secondary purpose of this review will be to compare methods used to integrate anxiety reduction interventions into pre-operative care and to evaluate the most widely used and effective strategy for clinical practice.

METHOD

A comprehensive review of the literature related to behavioral interventions versus pharmaceutical interventions to reduce preoperative anxiety in school aged children was conducted through the EBSCOhost databases, Medical Literature On-Line (Medline), Cumulative Index to Nursing and Allied Health Literature (CINAHL), and PsychInfo databases. Results were generated using the search terms ‘preoperative anxiety’, ‘children’, ‘outcomes’, ‘surgery’, and ‘interventions’ (Figure 1). Initial search revealed 198 result, with 144 of the studies immediately excluded for not meeting the inclusion criteria. Fifty-Four studies were selected for additional review and following in-depth analysis concluded 38 studies were excluded for not meeting the criteria. Articles in the inclusion criteria totaled 16. Additional studies and articles were selected after reviewing the synthesized articles for further clarity; making a total of 21. Inclusion criteria were peer reviewed articles published between 2006 and 2015 that focused on postoperative outcomes in which preoperative interventions to reduce anxiety in children two years and older prior to a surgical procedure was examined, as well as the parent’s perspective of the outcome. Exclusion criteria extended to articles with concentration on infants and children under the age of two years, and children with physical or mental disabilities. The data collected was analyzed and a synthesis of the effects and reduction of preoperative anxiety between behavioral and pharmaceutical interventions.

BACKGROUND

Preoperative anxiety

Induction of anesthesia can be very stressful for children. Changing a child's routines, unfamiliar faces, separation from family, lack in understanding hospital procedures and uncertainty, can cause severe anxiety (Chieng et al., 2013). Children are more vulnerable to anxiety for various reasons including an immature capacity to adapt, the fear of physical harm, separation anxiety and fear of feeling pain (Nilsson, Kokinsky, Nilsson, Sidenvall, & EnskÄR, 2009). Preoperative anxiety and stress are common emotions for any parent-child dyad prior to surgical procedures, but can be particularly harmful to children in the post-operative period. The level anxiety varies with a child's age and maturity. Children have been known to protest, cry, fight or even attempt to escape during induction of anesthesia (Drašković, Simin, & Kvrđić, 2015). The consequences of anxiety can manifest physiological responses such as an increased heart rate and cardiac irritability, which can lead to arrhythmias and other long-term complications such as decreased immunity, impaired wound healing and water/electrolyte imbalance (Manyande, Cyna, Yip, Chooi, & Middleton, 2015). Preoperative anxiety has been linked to the lack of quality sleep for up to 6 months postoperatively, which resembles the disease spectrum of posttraumatic stress disorder (Seiden et al., 2014).

Interventions aimed at minimizing anxiety and distress, while improving cooperation preoperatively can be of use to reduce adverse psychological and physiologic outcomes in the post-surgical setting (Cuzzocrea et al., 2013). Reducing preoperative anxiety can lead to beneficial postoperative outcomes such as reduction in hospital length stay, decreased recovery

times, enhancement of child and parent satisfaction, and decreased emergence delirium. Pharmaceutical and Behavioral therapies are the two primary interventions currently used to reduce preoperative anxiety in children (Chieng et al., 2013). The current available preoperative interventions to reduce anxiety include premedication of sedatives/midazolam prior to administering an anesthetic, allowing parents to be present during induction of anesthesia, and providing a hospital-based educational preparation program for the child and the parent before being admitted to the hospital for surgery. However, reports indicate that many children still experience preoperative anxiety, as all of the above interventions have adverse effects or limitations(J. H. Lee et al., 2014). In order to evade the impending side effects of drug interventions along with parental preference to avoid unnecessary medications; non-pharmacological/behavioral interventions have been established and tested to reduce preoperative anxiety with varying results.

Midazolam/ Pharmaceutical Intervention

Pre-anesthetic pharmaceuticals are often administered to children several hours prior to surgical procedures to assist with relaxation and cooperation with the health care team. Drug therapy that causes sedation and affects the central nervous system (CNS) can have undesirable side effects, such as respiratory depression, and can negatively alter physiologic well-being before anesthesia surgical procedure. Medications can also influence the child's mental status and level of consciousness during the recovery period following the surgery. In addition, there may be an added cost for a drug therapy intervention. The primary pharmaceutical agent used to

reduce anxiety in children prior to surgery is the administration of midazolam (Versed®), a benzodiazepine with sedative and amnestic effects. This drug can be administered orally, intravenously or intranasally. Intranasal midazolam has been compared to intranasal ketamine, another pre-operative anxiety medication, in reducing preoperative pediatric anxiety(Hosseini Jahromi, Hosseini Valami, Adeli, & Yazdi, 2012). The studies show intranasal midazolam was more effective than low- or high-dose intranasal ketamine in reducing preoperative pediatric anxiety (Hosseini Jahromi et al., 2012).

Midazolam, though proven effective in reducing preoperative anxiety in children, often has many undesirable and adverse effects such as desaturation, hypotension, and seizure like activity, nystagmus, and paradoxical reactions. Respiratory depression and cardio-pulmonary arrest has been associated with use of midazolam, especially when used for sedation in noncritical care settings(Hosseini Jahromi et al., 2012). Oral benzodiazepines can be challenging to administer in preoperative pediatric populations due to cooperation and adverse effects. In addition, paradoxical effects of benzodiazepines can also lead to preoperative agitation (Seiden et al., 2014). Thus leading health providers to consider and analyze the effectiveness and use of Non-pharmaceutical interventions.

Behavioral Interventions

A major limitation of pre-surgical interventions is the lack of a distraction platform that allows interaction with children prior to surgery(Manyande et al., 2015). Behavioral alternatives

to drug therapy have been tested to enhance the child's reduction of anxiety and increased cooperation at the beginning of their anesthesia (Fortier, Del Rosario, Martin, & Kain, 2010).

Behavioral interventions which have been analyzed and evaluated in the literature included; the presence of parents during pre-operative anesthesia induction, education about their procedure based on age appropriate learning implements, interaction of children with clowns, electronic devices with age appropriate games and music. Use of non-pharmacologic methods to decrease anxiety in children prior to surgery are less invasive and can potentially provide similar amounts of anxiety reduction with little to no side effects or adverse effects; thus leading parents and children more cooperative and willing to adapt the non-pharmaceutical intervention (Cuzzocrea et al., 2013).

Tablet/Electronic Devices

Interactive electronics has an effect on many aspects of healthcare. The transition that is being made to electronic devices is staggering. In every facet of society, we are using technology and hand held devices in all capacities of our daily activities. The use of a common, electrical device, such as a gaming device, smart phone, or tablet, can change how we choose to reduce preoperative anxiety in children. Electronic device interactions with children are crucial for the success of multi- media strategies to minimize depression or anxiety disorders. Interactive techniques have been proven superior to passive ones in pain perception in pediatric patients(Seiden et al., 2014).

A present study hypothesized that using a multimedia device/tablet/smart phone as part of a behavioral intervention can reduce preoperative anxiety, while taking into account individual characteristics, may be a simple, cost efficient and effective way to reduce preoperative anxiety in children. Limitations of this study have been sample size and methodology leading to imprecise or unclear answers(Manyande et al., 2015).

Music

Music is an important subject for research in the field of anesthesiology. Listening to music is one of several behavioral based methods to reduce pain and anxiety in both adults and children (Nguyen, Nilsson, Hellström, & Bengtson, 2010). There is increasing attention being afforded towards music therapy and music medicine as a non-pharmacological intervention to reduce preoperative anxiety. Music medicine involves passive listening to pre-recorded music that is offered by medical personnel. Whereas, music therapy is defined as the implementation of a music intervention by a trained music therapist that includes the therapeutic process and the use of personally tailored music experiences (Bradt, Dileo, & Shim, 2013). The use of music preoperatively is designed to reduce anxiety prior to anesthesia. Different theories are used to explain to this mode of action. One theory states that music reduces s-cortisol and also causes an increase in the levels of s-oxytocin. Another common theory refers music as a distracter; redirecting on the patient's attention away from negative stimuli to focus on something more enjoyable and cheerful. Relaxation from music can also be a pleasant distraction that serves as a mild sedative (Nguyen et al., 2010).

Music has been proven in postoperative pain management to be complementary method for reducing pain anxiety and stress. Music is considered a mild analgesic however it is relatively ineffective when the pain is severe (Matsota et al., 2013). Music is inexpensive, easy to administer and free of adverse effects. It can serve as a complementary method for treating preoperative anxiety even though music's effectiveness ultimately depends on the individual patient.

Clowns

An attempt to reduce pharmacological interventions for preoperative anxiety in children there has been an increase in the presence of clowns in pediatric hospitals. The success of this activity is possible if it is carried out by a professional artist having gone through careful and rigorous training programs. Rigorous training of the clowns in therapeutic communication can assist with creating a soothing environment that provides individualized care for the child; therefore, creating a greater effect than music during induction of anesthesia because of the child's involvement and actively performing with the clown. Thus generating an advanced level of distraction (Vagnoli, Caprilli, & Messeri, 2010).

Toys/Cartoons

The beneficial effects of viewing an animated cartoon and playing with a favorite toy can influence reduction in preoperative anxiety in children. The concept of distraction is a

predominant component of using this method of behavioral-based intervention. However the use of toys and watching cartoons prior to a surgical intervention tends to be more psychological than a distracter. Emotionally, the use of a cartoon of the child's choice and allowing them to play with and hold their favorite toy is based on comfort and familiarity, which can decrease stress. The child is in an unfamiliar environment with unfamiliar people, therefore allowing the child a toy from home and their favorite cartoon can reduce anxiety prior to a procedure or operative event. (J. Lee et al., 2012).

Surgery and anesthesia cause a significant amount of emotional stress in children. Since the consequences of this stress can extend to immediately after surgery and possibly continue even when the hospital treatment is over, the role of the anesthesiologist is to ensure psychological as well as physiological well-being of the child. In order to reduce emotional stress induced by anesthesia and operation, the anesthesiologist has to understand certain developmental phases that children go through and to identify situations which a child could potentially see as a danger or a threat (Drašković et al., 2015).

Children that frequently undergo surgery encounter stressful events. Separation from family, fear of the unknown, loss of control, unfamiliar faces, and fear of pain are all possible sources of stress. These sources will contribute to the child's anxiety level before and after surgery. A child's cognitive appraisal of the event will determine coping behaviors (Lazarus et al., 1974). How the child is able to cope with the stressors are affected by age, developmental level, prior hospitalizations, and prior encounters with the health providers (Brewer, Gleditsch, Syblik, Tietjens, & Vacik, 2006). Therefore, the use of the cartoon and favorite toy intervention was to establish familiarity and comfort for the child, thus reducing the preoperative anxiety.

Parental Presence

Many factors contribute to a child's preoperative anxiety. Separation from parents and the anxiety that it creates is thought to be one of the main contributors to preoperative anxiety in children. In some instances children are required to have physical limitations during induction due to the restlessness and unwillingness to separate from their parents. There are hospitals that have programs that include parental presence during induction of anesthesia and after surgery. Initial studies showed the parental presents could reduce children's anxiety and increase their cooperation. Parental presence during induction of anesthesia can considerably reduce child's anxiety when parents stay with their child. Children experience a more relaxed induction of anesthesia and less need for using drug therapy before the operation and experience less time for recovery along with higher satisfaction from parents. Prior studies show that children whose parents contribute to all dimensions of the care provided to the child had more optimal outcomes. However, other studies show that parental presence during induction of anesthesia did not improve the child's anxiety any more than the use of pre-operative drug therapy with midazolam. However, separation of children from their parents before entering the operating room is an important problem in children undergoing surgery. Parental presence during induction of anesthesia has been controversial and has had varying results regarding the child's anxiety reduction, other than reducing the parent's anxiety and satisfying the parents about the quality of care given to their child (Rasti, Jahanpour, & Motamed, 2014).

Summary

Health care professionals globally agree that less invasive interventions to reduce anxiety prior to a surgical procedure are optimal for children and adults alike. There are a variety of non-pharmaceutical/behavioral based interventions that have undergone trials to determine optimal effects to reduce preoperative anxiety in children (Fortier & Kain, 2015). Still encumbering their own limitations, multi-media/electronic devices, music, clowns, toys and parental presences can all contribute to aiding in the reduction of pharmaceutical interventions. Therefore, alternate interventions to drug therapy directed at anxiety reduction should be studied, analyzed and implemented on a grand scale, especially due to the absences of adverse effects.

RESULTS

Pharmaceutical

The review of the studies selected typically consisted of comparing a pharmaceutical intervention, midazolam, with various types of behavioral interventions in children. The bases of the studies were to comparatively analyze the reduction of pre-operative anxiety and which intervention yielded more significant results. A study regarding two different pharmaceutical interventions was reviewed to support the use of remaining studies that used midazolam.

A double blind study was conducted to compare the effects of intranasal midazolam versus different doses of intranasal ketamine on reducing preoperative pediatric anxiety(Hosseini Jahromi et al., 2012). The subjects' procedure was for elective surgery and randomly assigned to four equal groups. Pre operatively, the first group received midazolam 0.2 mg/kg, the second group (K1) ketamine 0.5 mg/kg, the third group (K2) ketamine 3 mg/kg, and the fourth group normal saline 1 drop/5 kg were administered intranasally. After 15 min, severity of anxiety was assessed with the modified Yale preoperative anxiety score (m-Yale PAS)(Hosseini Jahromi et al., 2012).

The mean of m-Yale PAS in midazolam group was significantly lower than the other three groups ($p < 0.05$) (Hosseini Jahromi et al., 2012). Therefore, support the remaining selection of studies that were reviewed using midazolam as the pharmaceutical of choice.

Child Life Specialist

Coping with a surgical procedure can be difficult for a child. A nurse or other health care professionals may have an impact on the child's ability to cope with the process. Children undergoing anesthesia and surgery have been described as having significant emotional reactions post-operatively (Copanitsanou & Valkeapää, 2014) . In an effort to minimize these reactions, health professionals developed preoperative educational preparation programs to familiarize patients with procedures and to facilitate coping (Fortier & Kain, 2015).

The study by source was a double blind study with $N=142$ children out of which $n= 80$ were experimental and $n=62$ were control. The purpose of this study was to determine if children prepared for day surgery by a child life specialist exhibited less anxiety than those who received routine standard of care.

The 80 children received formal preparation for their surgeries by a child life specialist. The control group of 62 children received no intervention. Children undergoing elective otolaryngology surgery completed the study. Children's anxiety was assessed by the "Child Drawing: Hospital" (CD:H) instrument – An instrument designed to measure the emotional status of hospitalized school-aged children (Brewer et al., 2006).

The preoperative average anxiety score the group ($n=86$) was 80 ($SD = 21$) for the patients without the child life intervention. The preoperative average anxiety score for the intervention group ($n=95$) was 89 ($SD = 20$) a significant difference from the nonintervention group, $t(179) = 2.89$, $p < .01$ (Brewer et al., 2006). The anxiety score change was significantly better for the patients in the child life intervention group than for those in the nonintervention

group. The increase in anxiety scores in the nonintervention group suggests that children could benefit from preoperative preparation.

Electronic Interactive technology

The growing popularity for technology will assist the health care community in integrating its various usages. A society as a whole has been labeled technology savvy; thus implying that many generations from young to old are exposed to and familiar with different types of technology; including smart phones, computers, tablets and television. Two studies were reviewed with the bases of technology.

A randomized clinical trial (n=120) was conducted to determine behaviorally oriented preoperative anxiety intervention program based on the anesthesia and psychology with smartphone application. The children were randomly placed into three equal groups; intravenous (IV) midazolam sedation (M group), smartphone application program (S group), and low dose IV midazolam plus smartphone application program (SM group). The modified Yale Preoperative Anxiety Scale (mYPAS) was used to evaluate the child's anxiety. The scale was used the holding area, 5 minutes after intervention and entrance to operating room (J. H. Lee et al., 2014).

After intervention, the mYPAS scores were lower than the preoperative holding area (M group 52.8 + 11.8 vs 41.0 + 7.0, S group 59.2 + 17.6 vs 36.4 + 7.3, SM group 58.3 + 17.5 vs 26.0 + 3.4). A comparison of mYPAS scores between each group showed that the S group reduced anxiety lower than M group ($P < 0.01$), and the SM group exhibited significantly lower anxiety than the two other groups ($P < 0.01$) (J. H. Lee et al., 2014). The behavioral intervention program

using a smartphone application effectively relieved anxiety in children and their parents within 5-10 minutes of the period between the preoperative holding area and entry into the operating room, and it also showed a superior effect compared with premedication (J. H. Lee et al., 2014). Concluding, the behavioral intervention showed a significant difference as opposed to the pharmaceutical intervention. However, the combination of both interventions presents the most significant results (J. H. Lee et al., 2014).

The second study was a randomized trial to compare the effects of a tablet-based interactive distraction (TBID) tool to oral midazolam on preoperative anxiety. The 108 children randomly selected a sealed envelope to one of the intervention groups; Midazolam Group or TBID Group (Seiden et al., 2014).

The TBID group was allowed to select an age appropriate videogame to play during the induction period starting at the time of parental separation and concluding at induction. The Midazolam group received the oral premedication at least 15 min and not more than 45 min prior to departure, to the operating room. There was a baseline period assessed at two points; parental separation and anesthetic induction. The Modified Yale Preoperative Anxiety Scale (mYPAS) was used to score anxiety levels (Seiden et al., 2014).

Other data collected included subject demographic characteristics, emergence delirium scores using the Post Anesthesia Emergence Delirium (PAED) Scale at emergence and 15 min after PACU admission, time-to-PACU arrival until awakening and time-to-PACU discharge. Parental perception of child anxiety was assessed at hospital arrival and at separation on a 7-point Likert scale ranging from 0 'not at all anxious' to 6 'very anxious'.

The mean difference (95% CI) in the increase of anxiety at parental separation between the TBID and the midazolam group was -9 (-2.6 to -16.4), $P = 0.006$, demonstrating superiority to midazolam group (one-sided $P = 0.003$). For children 2-11 years, the mean difference (95% CI) in anxiety at induction was significant between the TBID and midazolam groups, -14.0 (-6.1 to -22.0), $P < 0.001$. The median (IQR) time-to- PACU discharge was 111 (75-197) min in the midazolam group and 87 (55-137) min in the TBID group, $P = 0.03$ (Seiden et al., 2014).

The absolute emergence delirium score was significantly less between TBID and midazolam group and time to-PACU discharge was prolonged in the midazolam group. In the midazolam group, the median (IQR) time-to-PACU discharge was 111 (75–197) minutes whereas the TBID group was 87 (55–137) minutes. Postoperative behavior scores were not different between the groups at day 7 and 14, $P = 0.23$ and $P = 0.13$, respectively. Parents, 43 of 53 (81%) , of children in the TBID platform group were very satisfied with the child separation process compared with 22 of 37 (59%) in the midazolam group, $P = 0.02$ (Seiden et al., 2014).

The most significant finding in the study was the reduction of separation anxiety by a TBID tool when compared to oral midazolam. This finding was further supported by parental perception of lower anxiety and greater parental satisfaction in the TBID group compared with the midazolam group. With combined effects, it suggests TBID tool can be an effective strategy to minimize preoperative anxiety in children. This behavioral intervention proposes an effective and safe alternative to midazolam in the reduction of preoperative anxiety in children.

Music

Music therapy is defined by The American Music Therapy Association as the clinical and evidence based use of music interventions to accomplish individualized goals within a therapeutic relationship by a credentialed professional who has completed an approved music therapy program (Matsota et al., 2013). Music has been used for years to create a soothing and relaxing environment across all types of health care communities. In conjunction with anesthesia or pain medication, uplift a patient's mood and neutralize depression, calm or sedate, often to induce sleep, counteract apprehension or fear and lessen muscle tension for the purpose of relaxation, including the autonomic nervous system (Matsota et al., 2013).

A randomized clinical trial was conducted to evaluate if music medicine influences pain and anxiety in children undergoing lumbar punctures. The out of the 40 children selected 25 were boys and 15 were girls. The children were randomly assigned to 1 of the 2 groups: the music group (n = 20) or the control group (n = 20).

The Numeric Rating Scale (NRS) was used to measure the child's self-reported pain during 3 distinct phases: before, during, and after LP. The child rated the pain intensity on a scale, with point 0 being no pain and point 10 being the worst pain. The 6-item short form of the Spielberger State-Trait Anxiety Inventory (STAI) was used to measure anxiety. Secondary was the heart rate, blood pressure, respiratory rate, and oxygen saturation measured before, during, and after the procedure.

In the music group during and after the lumbar puncture the children presented lower pain scores, heart and respiratory rates. The anxiety scores after 10 minutes in the music group, but before LP, were significantly lower ($P < .001$) (mean = 8.6, SD = 2.78) than for the children

in the control group (mean = 13.25, SD = 3.73). There were no significant differences between the 2 groups with respect to age or gender and total time with earphones (Nguyen et al., 2010).

The second randomized clinical trial was to test whether postoperative music listening reduces morphine consumption and influence pain, distress, and anxiety and to describe the experience of postoperative music listening in school-aged children. There were 80 children selected for the trial in which they were allocated to music or control from of a randomized pack of cards. The music chosen, MusiCure ©, was soft and relaxing. Children with cognitive or hearing impairments were excluded from the study, as were children or parents who did not speak good Swedish and children who had dental or ear–nose–throat surgery (Matsota et al., 2013).

Objective pain scores (Face, Legs, Activity, Cry, Consolability [FLACC]), vital signs, and administration of anti-emetics were documented during postoperative recovery stay. The Coloured Analogue Scale [CAS]), distress (Facial Affective Scale [FAS]), and anxiety (short State-Trait Anxiety Inventory [STAI]) were recorded before and after surgery.

Children in the music group received less morphine in the postoperative care unit, 1/40 compared to 9/40 in the control group. Children's individual FAS scores were reduced but no other significant differences between the two groups concerning FAS, CAS, FLACC, short STAI, and vital signs were shown (Nilsson et al., 2009).

Clowns

Recent studies suggest the presence of a clown together with parental presence during induction of anesthesia was an effective intervention for reducing preoperative anxiety. However, the findings of this research offered in relevant literature were controversial, and therefore the view regarding the clown intervention was not an agreed upon to reduce anxiety in pediatric surgery (Vagnoli et al., 2010). The study investigated which intervention was more effective for reducing preoperative anxiety in children: a pharmacological intervention with midazolam or a behavioral intervention; such as the presence of Clowns plus parental presence or only parental presence (Golan, Tighe, Dobija, Perel, & Keidan, 2009).

A randomized trial was conducted with $n=75$ children. Each group, consisting of 25 children; group 1 the control group; group 2 the clown group and group 3 the parental presence group. In order to establish a baseline the study evaluated anxiety levels in the waiting room versus the preoperative room. The anxiety of children increased during the induction of anesthesia [$F(2,72) = 12.994$; $P = 0.001$]. The Modified Yale Preoperative Anxiety Scale (mYPAS) was used to score anxiety levels. The level of anxiety was significantly lower in the Clown Group compared to Parental Presence Group ($P = 0.038$) and to Control Group, whose level of anxiety was significantly higher ($P = 0.000$). There was not any significant difference between Control Group and Parental Presence. Additionally, there were no significant differences in the observed anxiety level between the three groups in the waiting room [$F(2,72) = 2.515$; $P = 0.005$]. In each group, there was an increased level of anxiety in the preoperative room in contrast with the waiting room; therefore this difference was statistically significant for the Clown Group and not the Control Group. The increased anxiety of Control Group was

significantly higher compared to Clown Group ($P = 0.000$), while there was no difference with Parental Presences Group ($P = 0.279$). In contrast, the anxiety of children in the Clown Group was significantly lower compared with both the other groups: CG ($P = 0.000$); PG ($P = 0.015$). In the three study groups there was no significant differences between the parents attending the induction of anesthesia (Vagnoli et al., 2010).

The study found that the use of preoperative medically trained clowns for children undergoing surgery can significantly alleviate preoperative anxiety compared to the Control Group and Parental presence group, however, clowns do not have any effect once the anesthesia mask is introduced (Golan et al., 2009). Research demonstrates clowns could be the most promising option to treat preoperative anxiety in children. It has proved more effective than only parental presence in reducing anxiety (Vagnoli et al., 2010). A clown can facilitate the induction process, leave a pleasant memory post-operative, and represent an alternative to midazolam to reduce anxiety in a child.

Toys/Cartoons

Children, in general, enjoy watching animated chows (cartoons). There is a comfort and familiarity when observing a cartoon of their choice. Most cartoons can be easily downloaded or accessed at no cost thus making it a viable option for a behavioral intervention to reduce preoperative anxiety. The study reviewed was conducted as a randomized trial with 130 children divided randomly into 3 groups; group 1 (control) and group 2 (toy) and group 3 (cartoon). The Modified Yale Preoperative Anxiety Scale (mYPAS) was used to score anxiety levels. The

principal finding of the study was the children who watched animated cartoons in the OR had significantly lower anxiety scores compared to the children in the control and toy groups. In addition, mYPAS and parent-recorded VAS scores of the majority of group 3 (animated cartoon) children were decreased or unchanged in the OR compared with the holding room, whereas the scores of most children in group 1 (control) and group 2 (toy) were significantly increased. There were significant correlations between mYPAS and parent-recorded VAS scores in all groups in the OR (group 1: $r = 0.670$, $P < 0.001$; group 2: $r = 0.760$, $P < 0.001$; group 3: $r = 0.634$, $P < 0.001$; overall: $r = 0.789$, $P < 0.001$)(J. Lee et al., 2012). Therefore, the study presents data concluding that by simply watching a cartoon to create a distraction and feelings of comfort and familiarity can significantly decrease a child's preoperative anxiety.

Parental Presence

Logically we would expect that a parent being present and “comforting” to their children prior to a surgical procedure would be an appropriate intervention to reduce children's preoperative anxiety. However, research shows different. The presence of parents to reduce preoperative anxiety is controversial: numerous studies underline the benefits of this intervention stating it helps reduce the use of premedication and increase child cooperation, whereas others studies point out the possibility that it may increase parental anxiety and child behavioral problems (Vagnoli et al., 2010). Another study show that it can actually create more anxiety for the child if the parent themselves has a heightened anxiety level at that time (Golan et al., 2009).

The study analyzed for this review was a randomized trial conducted with 60 children randomly divided into 2 groups; a control and experimental group; the experimental group being the group with parental presence. The Modified Yale Preoperative Anxiety Scale (mYPAS) was used to score anxiety levels. There was no significant difference between mean total score of children's anxiety in the control group (70.39 ± 20.93) and the experimental group (67.83 ± 16.78) before surgery ($p > 0.05$). Furthermore, there was no significant difference among changes in children's anxiety total score in the control group (-3 ± 16.45) and in the experimental group (-8.39 ± 22.95) before and after surgery ($p > 0.05$) (Rasti et al., 2014).

Supporting the findings in this study, other relevant studies show no significance in parental presence. Parental presence is routinely used in some hospitals while actively discouraged in others (Vagnoli et al., 2010). Unfortunately, despite natural instinct, it seems that the presence of parents has no useful and significant effect on children's preoperative anxiety thus in order to reduce complications due to surgery anxiety, other effective interventions should be investigated.

DISCUSSION

The studies and literature examined for this thesis can offer insight into behavioral interventions and the variety that is available. Research findings showed the role and potential use of implementing behavioral interventions to reduce preoperative anxiety in children. Although the reviewed literature presented mixed results, the use of behavioral interventions reveal several beneficial effects on reducing preoperative anxiety by post-surgical and financial optimal outcomes.

Reducing or eliminating preoperative anxiety in the child is essential to lessen maladaptive post-surgery outcomes, along with a child's damaging views of medical care. The increase in preoperative anxiety is associated with increased postoperative pain, analgesic consumption, general anxiety, and behavioral problems (St. Onge, 2012). It is also clinically important because preoperative anxiety has been implicated with worse postoperative recovery in surgical patients (Seiden et al., 2014). Oral benzodiazepines (midazolam) are likely the most common premedication used by health care providers to minimize preoperative anxiety in children. However, oral benzodiazepines can be difficult to administer in children along with potentially causing adverse effects such as; paradoxical effects of benzodiazepines which can lead to preoperative agitation (Seiden et al., 2014).

Due to the economic impact that prolonged time-to PACU discharge has on institutions; the findings in several trials are important. Subjects showed a shorter time to discharge with behavioral interventions opposed to pharmaceutical (Seiden et al., 2014). Conversely, the behavioral interventions reduce separation anxiety while still promoting an earlier discharge and

optimal outcomes. The studies and reviews have not consistently shown parental presence to reduce pre-operative anxiety in children. This should warrant further studies.

The current study shows that child life preparation can continue to minimize children's anxiety up to 1 month postoperatively. Even with the limitation of a wide range of time between preoperative and postoperative drawings, the data analysis showed no correlation between length of time and the anxiety score differences in this study. Additional research on children's anxiety in the postoperative period would be beneficial (Brewer et al., 2006).

Using Piaget's stages of intellectual development, children's ages should be taken into consideration with further studies. A child at the age of 2 will not perceive nor report the situation the same as would an 8 year old; as an 8 year old would not the same as a 15 year old. All these variables support that children in different cognitive stages need to be prepared based on their developmental level along with the behavioral intervention selected (Perry, Hooper, & Masiongale, 2012).

In combination with the studies reviewed, despite limitations and variables, there was a consistency in findings with significant differences in using behavioral interventions to reduce preoperative anxiety in children. The behavioral interventions can decrease hospital stay, reduce anxiety, promote optimal health related outcomes, and provide parent satisfaction while improving the financial status of the institution. Studies should be conducted on behavioral interventions based on a child intellectual development to help establish a more exact protocol on the proper behavioral intervention.

Even though the articles did not discuss the financial barriers that should be considered for some of the behavioral interventions; it should be reviewed for successful implementation.

Recently introduced interventions using tablets, smart phones, and cartoons are appropriate intervention programs for meeting this purpose (J. H. Lee et al., 2014). These technological devices however, have additional advantages. Smartphone applications and tablets are owned by many people, especially parents; hence, the hospital does not need to secure additional devices therefore relieving some of the financial burden. In addition, such devices can lead to an effective reduction of anxiety with short training on the day before surgery, even in children without previous exposure to the devices. However, if additional devices are needed, the cost could be considerably less than an extended stay caused by the preoperative anxiety. Whereas, behavioral interventions; such as parental presence and playing with favorite toy, bare no additional cost to the health care facility.

In conclusion, there should be further studies to help create and implement appropriate protocols. However, with evidence present within the studies reviewed, it is respectively accurate to conclude that it is imperative as nurses to use behavioral interventions to help reduce preoperative anxiety. Furthermore, none of the studies presented any evidence that behavioral interventions had adverse effects, therefore making it seemingly senseless, not to at least try other or additional behavioral interventions along with pharmaceutical interventions to enhance post-operative outcomes.

LIMITATIONS

In this literature review, several limitations were noted. The preliminary search exposed copious findings related to the key words; anxiety, interventions, pediatrics, children, preoperative, outcomes, premedication, non-pharmaceutical, surgery; thus presenting with irrelevant research articles and clinical trials for the purpose of this review. Therefore, a more narrow search was established using the key terms; anxiety* AND pediatric or child* AND Intervention, preoperative or surgery. When additional keywords were used such as clowns, music, tablets/smartphone the results were limited and irrelevant. This finding supports and indicates the need for future research in the comparison of pharmaceutical versus non pharmaceutical interventions.

Several of the studies were limited by time, included a small sample size, lack of data on time of induction, and to know whether there were any differences in adverse behavioral responses in the week post discharge for each group. The studies targeted children, but each study had a varying age range and was not consistent. However, all the studies were with children under the age of 16 and over the age of 1. Many of the studies showed no overall differences in age. However, children aged between 8 and 11 years process cognitive information which based on Piaget's stages of intellectual development falls into the concrete operational period. Meaning that in this stage they are less egocentric, more logical, and have the ability to project others' experiences onto themselves. Their environment and observations of surrounds and television impacted their thought process, in turn can impact their baseline

anxiety. Whereas, children aged 5- 7 years of age are intuitive thinkers who focus more on personal perceptions rather than objective principles (Brewer et al., 2006).

The largest sample size was $n=142$ and was limited to the elective otolaryngology surgery only; whereas the smallest sample size $n=40$ was limited to lumbar puncture procedure. In all trials, the subjects were excluded if there was a documented behavioral or psychiatric disorders or the procedure was emergent. Some of the trials limited to naive induction patients. In one trial, even though the parent's consent to the trial, four children were eliminated because they did not bring in a toy from home. Due to the nature of the examined intervention, one trial could not ensure that the data collection process was blinded and cannot completely exclude measurement bias (Seiden et al., 2014).

RECOMMENDATIONS FOR PREOPERATIVE INTERVENTIONS TO REDUCE ANXIETY IN CHILDREN

Behavioral interventions to reduce preoperative anxiety in children can range from parental presence to technological apparatuses. Even though there are different studies in which the application of different behavioral interventions to assess which one is the most effective in different age group and cultures; the studies reviewed shared a common theme; reduction of preoperative anxiety.

Therefore, in future studies it would be adventitious to compare the four predominate behavioral interventions with and without premedication of midazolam along with comparison in developmental age.

The behavioral interventions that were reviewed share a common familiarity to children and would typically create a sense of happiness, comfort and wellbeing. Thus using any variety of the behavioral interventions can help reduce a child's anxiety level. The literature suggests that the behavioral intervention used in each study had some degree of significance and showed correlation to the parent's satisfaction as well.

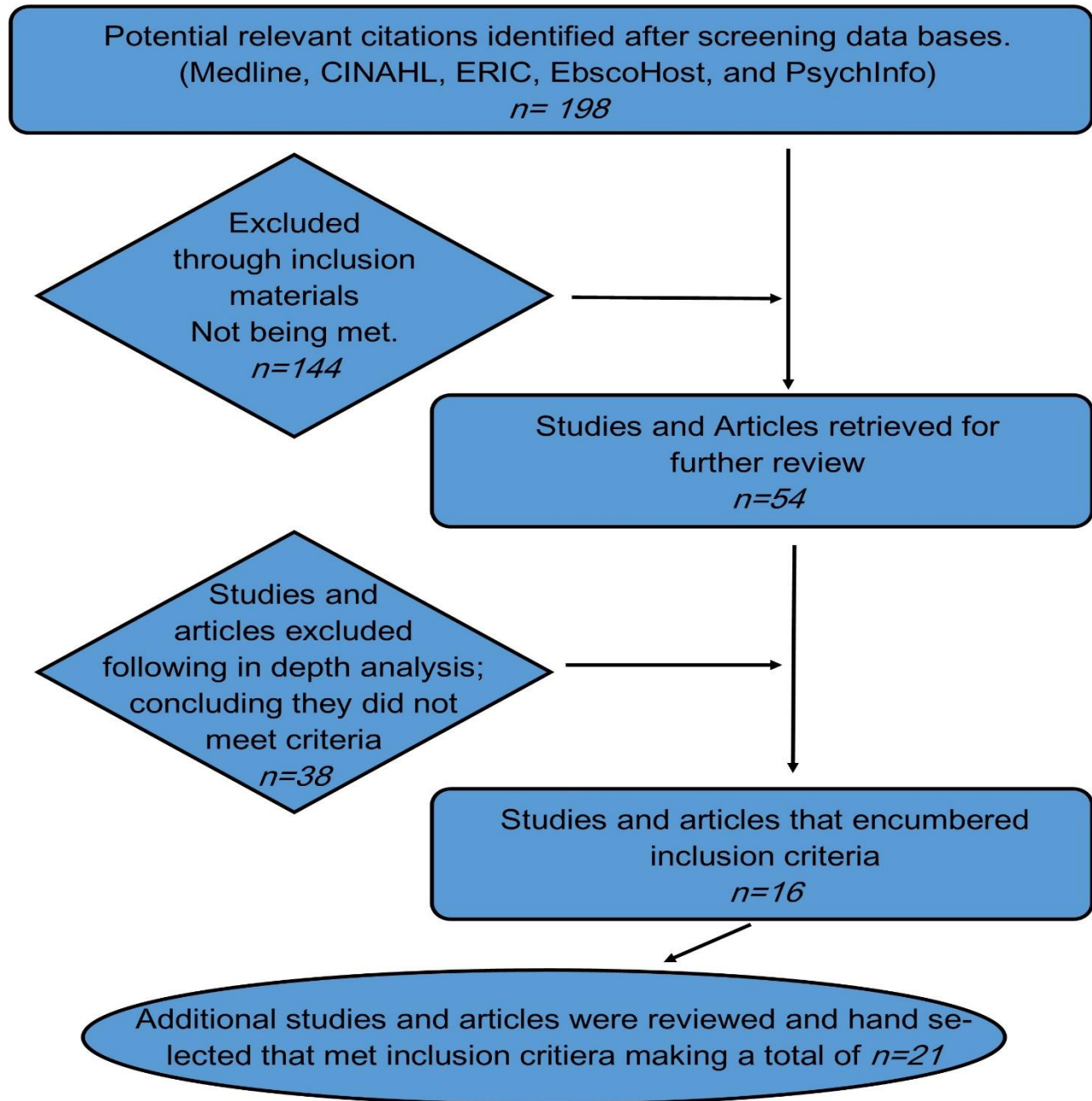
In one study the length of emergence to discharge time was reduced. The shortened hospital stay leads to optimal financial benefits for the hospital. Therefore, mentally and physically being a more optimal outcome for the patient and the hospital also. Other research explained that lower dosages of premedication along with a behavioral intervention can also conclude optimal results; thus leading to a reduction in medication cost. In addition to the current research and for the added financial benefit for the medical facilities involved; further

studies should be conducted looking at the role that behavioral interventions play in increasing financial benefits.

Nursing has a commitment to use evidence-based research and to be knowledgeable regarding new findings, current studies and to disseminate information for their health care facility. Nurses are trusted to make assessments, evaluations and judgment calls based on sound evidence. In conjunction with patient care; nurses should be of special concern to contribute to changes in the healthcare community. Nurses can help create and establish protocols and best practices for integration of behavioral interventions to reduce preoperative anxiety in children. Nurses will be able to assess his or her patient and customize a behavioral intervention that produces optimal outcomes based on research. Patient care can be enhanced by achieving optimal post-surgical outcomes for the patient and their parent; in addition to lowering the healthcare facilities cost.

Appendix A

Figure 1



Key Search Terms: Anxiety* AND Pediatric OR child* AND Intervention, Preoperative OR Surgery

Limiters: English Language, Peer Reviewed, Published 2006-2015

Appendix B

Table of Evidence

| Author(s) Year Location | Study Design And Purpose | Sample Size | Intervention Protocol | Screening Measures | Outcome Measures | Key Findings and Limitations |
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| Brewer, Stephanie Gleditsch, Shannon L. Syblik, Dorothy Tietjens, Mary E. Vacik, Heidi W. 2006 United States | Double Blind To determine if children prepared for day surgery by a child life specialist exhibited less anxiety than those who received routine standard of care. | $n=142$ $n=80$ (experimental) $n=62$ (control) | 80 children received formal preparation for their surgeries by a child life specialist. 62 received no intervention. | Ages 5-11 Children undergoing elective otolaryngology surgery completed the study. | Children's anxiety was assessed by the “Child Drawing: Hospital” (CD:H) instrument Child Drawing: Hospital – An instrument designed to measure the emotional status of hospitalized school- aged children. Journal of Pediatric Nursing was used to determine children's anxiety levels pre- intervention and post-intervention. | The preoperative average anxiety score was 80 ($SD = 21$, $n =$ 86) for the patients without the child life intervention. The preoperative average anxiety score for the intervention group was 89 ($SD =$ 20, $n = 95$), a significant difference from the nonintervention group, $t(179) = 2.89$, $p <$.01. The anxiety score change was significantly better for the patients in the child life intervention group than for those in the nonintervention group |
| Hosseini Jahromi, S. Hosseini Valami, S. | Double Blind To compare the effects of | $n=120$ | Elective surgery and randomly assigned to four equal groups. | Aged 2-8 Children undergoing | After 15 min, severity of anxiety was assessed with the modified Yale | The mean of m-Yale PAS in midazolam group was significantly lower than the other |

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| Adeli, Nematollah Yazdi, Zohreh 2012 Iran | intranasal midazolam versus different doses of intranasal ketamine on reducing preoperative pediatric anxiety | | First group midazolam 0.2 mg/kg, Second group (K1) ketamine 0.5 mg/kg, Third group (K2) ketamine 3 mg/kg, Fourth group normal saline 1 drop/5 kg were administered intranasally. | elective surgery | preoperative anxiety score (m-Yale PAS) Level of sedation was evaluated by the Ramsay Sedation Scale before intravenous catheterization | three groups ($p < 0.05$). Regarding this score, there was no significant statistical difference between K2 and normal saline groups ($p =$ 0.944), but the differences between K1 and K2 ($p = 0.034$) and also between K1 and normal saline ($p =$ 0.049) groups were significant statistically. |
| Lee, Jeongwoo Lee, Jihye Lim, Hyungsun Son, Ji-Seon Lee, Jun-Rae Kim, Dong-Chan Ko, Seonghoon 2012 South Korea | Randomized Clinical Trail To determine the beneficial effects of viewing an animated cartoon and playing with a favorite toy on preoperative anxiety in children | $n = 130$ <i>Group 1: 44</i> <i>(control)</i> <i>Group 2:</i> <i>40(toy)</i> <i>Group 3: 42</i> <i>(animated</i> <i>cartoon)</i> | Randomly assigned to 1 of three groups: First group was the control: Group two was asked to bring in their favorite toy Group three was asked to pick 1 | Ages 3-7 ASA physical status I or II Previous sedation, mental retardation or emergency surgeries were excluded. | Preoperative anxiety was determined by the modified Yale Preoperative Anxiety Scale (mYPAS) Parent-recorded anxiety Visual Analog Scale (VAS) the night before surgery, in the preanesthetic | 4 children in group 2 were eliminated because they did not bring in a toy. Group 2 mYPAS and parent-recorded anxiety VAS scores were significantly lower than those of groups 1 and 3 (mYPAS: $P = 0.007$; Parent-recorded anxiety |

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| | | | from 10 selected children's movie | | holding room, and just before anesthesia induction | <p>VAS: $P = 0.02$).</p> <p>In the OR, children in group 3 had the lowest mYPAS and parent-recorded anxiety VAS scores (mYPAS: $P < 0.001$; parent-recorded anxiety VAS: $P < 0.001$).</p> <p>In group 3, the mYPAS and parent-recorded anxiety VAS scores of only 3 and 5 children were increased in the operating room compared with their scores in the pre-anesthetic holding room, whereas the anxiety scores of 32 and 34 children in group 1 and 25 and 32 children in group 2 had increased ($P < 0.001$). 3</p> |
| Lee, J. H. Jung, H. K. Lee, G. G. Kim, H. Y. Park, S. G. | Randomized Clinical Trial To determine behaviorally | $n = 120$ | Randomized the patients into three groups Intravenous (IV) | Aged 1-10 for elective surgery | The modified Yale Preoperative Anxiety Scale (mYPAS) at holding area, 5 min after | The mYPAS after intervention were lower than the preoperative holding area (M group 52.8 + 11.8 vs 41.0 + |

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| Woo, S. C. 2014 South Korea | oriented preoperative anxiety intervention based on the anesthesia and psychology with smartphone application. | | midazolam sedation (M group), Smartphone application program (S group), Low dose IV midazolam plus smartphone application program (SM group). | | intervention, entrance to operating room. | 7.0, S group 59.2 + 17.6 vs 36.4 + 7.3, SM group 58.3 + 17.5 vs 26.0 + 3.4). A comparison of mYPAS scores between each group showed that the S group reduced anxiety lower than M group ($P < 0.01$), and the SM group exhibited significantly lower anxiety than the two other groups ($P < 0.01$) |
| Nguyen, T. N. Nilsson, S. Hellström, A. Bengtson, A. 2010 Hanoi, Vietnam | Randomized Clinical Trial To evaluate if music medicine influences pain and anxiety in children undergoing lumbar punctures. | $n=40$ | 40 children 25 boys 15 girls, Randomly assigned to 1 of the 2 groups: The music group ($n = 20$) or the control group ($n = 20$) | Aged 7-12 for lumbar puncture procedure only | The Numeric Rating Scale (NRS) was used to measure the child's self-reported pain during 3 distinct phases: before, during, and after LP. The child rated the pain intensity on a scale, with point 0 being no pain and point 10 being the worst pain. The 6-item short form of the | Lower pain scores, heart and respiratory rates in the music group during and after the lumbar puncture. The anxiety scores after 10 minutes of music medicine, in the music group, but before LP, were significantly lower ($P < .001$) for the children in the music group (mean = 8.6, SD = 2.78) than for the children in the control |

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| | | | | | <p>Spielberger State-Trait Anxiety Inventory (STAI) was used to measure anxiety.</p> <p>Secondary was the heart rate, blood pressure, respiratory rate, and oxygen saturation measured before, during, and after the procedure.</p> | <p>group (mean = 13.25, SD = 3.73)</p> <p>No significant differences were found between the 2 groups with respect to age or gender and total time with earphones.</p> |
| <p>Nilsson, Stefan Kokinsky, E. V. A. Nilsson, Ulrica Sidenvall, Birgitta EnskÅR, Karin</p> <p>2009</p> <p>Sweden</p> | <p>Randomized Clinical Trial</p> <p>To test whether postoperative music listening reduces morphine consumption and influence pain, distress, and anxiety after day surgery and to describe the experience of postoperative music listening in school-aged children who had</p> | <p><i>n</i>=80</p> | <p>80 children</p> <p>Protocols were allocated to music or control from of a randomized pack of cards.</p> <p>40 randomized to the “music” group</p> <p>The music chosen, MusiCure ©, was soft and relaxing.</p> <p>40 randomized to</p> | <p>Aged 7–16</p> <p>Children with cognitive or hearing impairments were excluded from the study, as were children or parents who did not have a good command of Swedish and children who had dental or ear–nose–throat surgery</p> | <p>Objective pain scores (Face, Legs, Activity, Cry, Consolability [FLACC]), vital signs, and administration of anti-emetics were documented during postoperative recovery stay.</p> <p>Coloured Analogue Scale [CAS]), distress (Facial Affective Scale [FAS]), and anxiety (short State-Trait</p> | <p>Children in the music group received less morphine in the postoperative care unit, 1/40 compared to 9/40 in the control group.</p> <p>Children’s individual FAS scores were reduced but no other significant differences between the two groups concerning FAS, CAS, FLACC, short STAI, and vital signs were shown</p> |

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| | undergone day surgery. | | the control group | | Anxiety Inventory [STAI] were recorded before and after surgery | |
| Rasti, R. Jahanpour, F. Motamed, N. 2014 Iran | Randomized Clinical Trial To examine the effect of parental presence on anxiety during anesthesia induction in children 2 to 11 years of age undergoing surgery. | <i>n</i> =60 | 60 children 30 children randomized to the “control” group. 30 Children randomized to the “Case” group Case group: Parental presence prior to induction until complete sedation and upon emergence in recovery room | Age range of 2-11 years, Lack of chronic diseases (cancers and liver or renal diseases), Good sense of hearing and the ability to talk, Having age-appropriate cognitive abilities, Having father, mother, or a specific custodian at the time of admission and hospitalization No experience of operation in the past. No history of central nervous system diseases and mental disorders | Demographic specification questionnaire and modified-Yale preoperative anxiety scale | Different in terms of the state anxiety or irritation (P=0.03) and dependence on parents (P=0.03), as the case group performed more favorable than the control group There was no significant difference between the two groups in terms of activity (P=0.3), expression of emotions (P=0.5), tone of voice (P=0.3), the state anxiety or irritation (P=0.8), and dependence on parents (P=0.4) after the operation The paired test showed no significant difference between the case and control groups in terms of the mean total score |

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| | | | | | | for children's anxiety before and after the operation (P=0.055) |
| Seiden, Samuel C. McMullan, Susan Sequera-Ramos, Luis De Oliveira, Gildasio S. Roth, Andrew Rosenblatt, Audrey Jesdale, Bill M. Suresh, Santhanam 2014 United States | Randomized Trial To compare the effects of a tablet-based interactive distraction (TBID) tool to oral midazolam on preoperative anxiety | <i>n</i> =108 | A randomly selected sealed envelope to one of the two intervention group Midazolam Group TBID Group TBID group were allowed to select an age appropriate videogame to play during the induction period starting at the time of parental separation and concluding at induction. Midazolam group received the oral premedication at least 15 min and | Aged 1-11 outpatient surgical procedures; American Society of Anesthesiologists Physical Status (ASA-PS) score I or II and first time anesthetic for the patient. Subjects were excluded if there was a documented behavioral or psychiatric disorders or the procedure was emergent | Baseline period assessed at two points parental separation and anesthetic induction. Modified Yale Preoperative Anxiety Scale (mYPAS) Other data collected included subject demographic characteristics, emergence delirium scores using the Post Anesthesia Emergence Delirium (PAED) Scale at emergence and 15 min after PACU admission, time-to-PACU arrival until awakening and time-to-PACU discharge. Parental perception | The mean difference (95% CI) in the increase of anxiety at parental separation between the TBID and the midazolam group was -9 (-2.6 to -16.4), P = 0.006, demonstrating superiority to midazolam group (one-sided P = 0.003). For children 2-11 years, the mean difference (95% CI) in anxiety at induction was significant between the TBID and midazolam groups, -14.0 (-6.1 to -22.0), P < 0.001. The median (IQR) time-to- PACU discharge was 111 (75-197) min in the midazolam group and 87 (55-137) min in the TBID group, P = 0.03. |

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| | | | not more than 45 min prior to departure to the operating room | | of child anxiety was assessed at hospital arrival and at separation on a 7-point Likert scale ranging from 0 'not at all anxious' to 6 'very anxious'. Parental satisfaction with child separation was assessed by asking parents on 'how satisfied are you with the ease with which your child got separated from you?' and using a Likert scale ranging from 0 'very satisfied' to 6 'not satisfied' | |
| Vagnoli, Laura Caprilli, Simona Messeri, Andrea 2010 Italy | Randomized Clinical Trial To investigate which intervention is more effective in reducing preoperative anxiety | <i>n</i> =75 3 separate groups | Randomly assigned: <i>n</i> =25 Clowns group (accompanied to the preoperative room by the clowns and by a parent) | Aged 5-12 children who were classified as physical status I-II according to the American Society of Anesthesiologist s standards and | Modified Yale Preoperative Anxiety Scale (m- YPAS). Parental anxiety was measured by using the State-Trait Anxiety Inventory (STAI Y-1/Y-2) | No significant differences between the parents attending the induction of anesthesia The level of anxiety was significantly lower in the Clown Group compared to Premedication Group (P = 0.038) and to CG, |

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| | <p>Interventions: Midazolam, Parental presence, Clown presence</p> | | <p><i>n</i>= 25 Premedicated with 0.5 mg/kg oral midazolam group (accompanied to the preoperative room by one parent)</p> <p><i>n</i>= 25 Control group only accompanied by one parent</p> | <p>who were scheduled to undergo general anesthesia for minor surgery</p> <p>Children with a history of chronic illness, premature birth, developmental delay, or previous anesthetic experience were excluded from this study</p> | <p>whose level of anxiety was significantly higher (<i>P</i> = 0.000).</p> <p>The Clown group was significantly less anxious during the induction of anesthesia when compared with the control and premedication group. There were no significant differences between the level of anxiety in the two rooms in children who were accompanied by clowns.</p> |
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